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RESEARCH ARTICLE

QUALITY OF LIFE IN PATIENTS WITH MIGRAINE, RECEIVING A HOMEOPATHIC TREATMENT (ARNICA MONTANA LINN.) - A SHORT TERM PROSPECTIVE STUDY.

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Abstract

Background: Migraine is chronic neurovascular disorder which affects the quality of life. **Design:** It was single centric, parallel, randomised, single blinded, placebo-controlled clinical trial conducted on patients of migraine. **Experimental work:** 130 patients were enrolled in the study. By randomised technique 65 patients were placed in placebo group and 65 patients were placed in treatment group. The study was conducted for 4 months at Meghani Homeopathy Hospital, Rajkot. Demographic data, Improvement in Quality of Life in the two groups were compared. **Statistical analysis used:** Based on the normality of data, unpaired t test or Mann Whitney U test was used for comparison of changes in SF-36 scores for Quality of Life. **Result and discussion:** Female in gender, working age of people and common migraine (unilateral side) was found to most prevalent in Rajkot region. Comparison of 0 and 120 days showed marked decrease in frequency, duration and intensity of attack significantly. SF-36 scale showed significant increase in treatment group after 120th day treatment from placebo group. These scales differences were statistical significant ($P < 0.05$) except the mental health as compared to placebo group. PCS (Physical Component Summary) and MCS (Mental Component Summary) both were found to increase in treatment group 48.49 ± 0.68 and 46.18 ± 0.685 as compared to placebo group 30.3 ± 1.02 and 42.60 ± 0.69 (120 days). The increase in PCS and MCS was significant statistically ($P < 0.05$). **Conclusion:** Arnica- 30c a homeopathic formulation at the end of 120 days was found to improve Quality of Life in patients of migraine.

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Introduction:-

Migraine is a neurovascular disease which has characteristic recurrent attack of severe headaches with nausea, vomiting and sensitivity to light or sound, etc. According to WHO and American Headache Society 12-15% of total population are suffering from migraine. Considering the fact that migraine is a poorly diagnosed disease, prevalence of migraine still can be higher. Such high prevalence contributes to huge socio-economic burden and adversely affect quality of life in patients of migraine. Current therapies such as triptans may produce adverse effects like coronary/ peripheral vasoconstriction, dysrhythmias, nausea, vomiting, chest tightness, etc. NSAIDs like aspirin, paracetamol can produce temporary relief in pain of migraine and their chronic use causes many adverse effects. Thus use of allopathic medication is unsatisfactory and may produce adverse effects which limits its usefulness.

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Thus, there is urgent need of safe and effective therapy belonging to complementary and alternative medicines in treatment of migraine. Homeopathic treatment is controversial therapy used for ailment of many diseases. It is found to have more beneficial effects in various diseases which are either incurable and/or where current medication leads to adverse effect or unsatisfactory responses. Migraine, gout, allergic rhinitis, asthma, vertigo are few of such examples. ⁶*Arnica montana* is reported to be used in many diseased conditions including pain and inflammation, alone as well as in combination with other herbs. ⁷Helenalin, a sesquiterpene lactone, is main constituent of *Arnica montana* reported to show beneficial effects in pain and inflammatory disease. Few clinical trials also demonstrated the effectiveness of *Arnica montana* in USA ¹ when used in a polyherbal formulation. Arnica 30c (a homeopathic formulation) is, used by many homeopathy practitioners, gives satisfactory and beneficial effects in patients. Results of one of retrospective study involving use of Arnica 30c showed good prognosis with improved quality of life in patients of migraine. No clinical study is yet being conducted to assess the effectiveness of Arnica 30c in migraine. ²SF-36 is a valid tool used for evaluation of the quality of life in patients. Thus, present clinical study is designed to assess quality of life in patients with migraine receiving homeopathic treatment (i.e. Arnica 30c) with prospective approach.

Materials and Methods:-

Study Design⁴:-

Parallel, Simple Sequential Randomization, Blinding (Single blinded), Placebo controlled, Single centric, Prospective study.

Parallel: It means randomized two group of patients will receive either placebo or treatment group, the group receiving the treatment or placebo will not be crossed among another groups, means the treatment group will receive treatment with arnica not with placebo.

Simple Sequential Randomization: It is like head or tail in tossing of coin, the subjects will be allocated randomly in equal manner as per investigator. Randomly subjects will get either treatment group or placebo group.

Single blinding: Blinding means masking something. It means in this study the investigator knows the identity of treatment or placebo group but the subjects don't know. It is used for minimizing the bias.

Placebo controlled: A placebo is an inactive or a dummy medication, which is given to increase the scientific validity in study. A placebo is included in the study to remove the psychological factor from the patient that the effect of progress in migraine is due to drug only. A placebo group of patients with the treatment group of patients are then analysed.

Sample Size³:-

For calculating sample size we deal with the proportions like morbidity rates, cure rates, vaccinated, dies, survived etc. For calculating suitable sample size assumption is made is that allowable error does not exceed 10% or 20% of the positive character. The size can be calculated by following formula:

$$N=4pq/L^2$$

p= positive character

q= negative character=1-p,q= 100-p in percentage as p+q=100

L=allowable error of p, usually 10% to 20% of positive character.

Inclusion criteria:-

All patients of migraine between the ages of 18 and 65 years are included in these trials.

Patients who are regularly follow up.

Patient having migraine with aura (Classic Migraine) and Migraine without aura (Common migraine) both are inclusive additionally patients with unilateral and bilateral pain are also included in these trials.

Exclusion criteria:-

Patients who are hypersensitive to homeopathic treatments are excluded from the trial.

Patients who are already receiving Arnica 30c are excluded from the trial.

Patients who don't follow up time to time are excluded from the trial.

Patients with normal headaches or cold related headaches are excluded from the trial.

Special population like Geriatrics, Pediatrics, Pregnant women, and lactating women are excluded from trail.

Patients having pathological condition is hypertension, thyroid and diabetes mellitus which are excluded. Female before puberty, during menstruation, menopause are excluded.

Methodology:-

Quality of life in migraine was measured as per SF-36 questionnaires².

From the review of previous published journals, the questionnaire was obtained and made from the consulted of physician for determining the demographic characteristics of patients. The study was conducted for four months' duration. Randomized group of people were received placebo and arnica treatment and then comparison with placebo will be analysed.

Table 2.1:- Schedule for study

Days	Schedule
0	Patient Enrolled and SF-36 Questionnaires fill up
30	First Follow up
60	2 nd Follow up & SF-36 Questionnaires fill up
90	3 rd Follow up
120	4 th Follow up & SF-36 Questionnaires fill up

The SF-36 questionnaire is composed of 36 questions that explore many aspects of the physical, psychic and relational health of the patient. The answer to these questions are processed in order to obtain eight different scores, representing eight different concepts related to health:²

- ❖ Physical functioning (PF)
- ❖ Role limitations due to physical problems(RP)
- ❖ Bodily pain (BP)
- ❖ General Mental Health (MH)
- ❖ Role limitations due to emotional problems (RE)
- ❖ Vitality (VT)
- ❖ Social functioning (SF)
- ❖ General Health (GH)

These scores can be statistically evaluated, according to the parameters expressed above. The difference between results of (0,30,60,90,120) days were analysed by statistical method. The SF-36 is designed for use in those at risk each parameter is score from 0 to 100.

Ethical Ethics Committee, department of Pharmaceutical Science, Rajkot approved the project on clinical studies. The study was conducted after the review from the committee.

Data Collection:-

The data was collected from Meghani Homeopathic hospital, Rajkot. The result are calculated according to the symptomological & subjective data obtained through patients by using SF-36 QoL (Quality of Life) questionnaire and later analysis are done. Additionally, we checked the demographic data of patients like gender, age and marital status; types of migraine such as classic migraine, common migraine; and disease characteristics of patients like number of migraine attacks per month, intensity of attacks, and duration of attacks.

Statistical Analysis:-

Collected data will be represented as Mean \pm SEM followed by evaluation by applying appropriate statistical analysis. Data for all parameters was first subjected to test of normality (Graphpad Instat version 7.0).⁸ SF-36 Data which shows normal distribution was analysed by using parametric tests (Unpaired student's t test) and that shows non-normal distribution was analysed through non-parametric tests (Mann- Whitney U test) where P<0.05 was considered to be statistically significant. Accordingly, Physical functioning, Bodily pain, General Health, Role Emotional, Role Physical and Social Functioning were analysed through Mann- Whitney U test whereas Physical Component summary, Mental Component Summary, Mental Health and Vitality were analysed through unpaired t test. Scoring in SF-36: In statistical analysis, once the questionnaire has been completed by the patients, it was analysed with scores and it was converted in the transformation score. Then the proper statistical method is applied where P<0.05 was considered statistically significant. Two sets of score will be derived from SF-36: eight section scores of SF-36, and two summary scores, one of the physical components a (PCS) and one for the mental components (MCS) summary scores. For each set of scores, two alternative approaches may be used in calculating

scores: a normal, additive approach that produces 0 to 100 scores for the eight studies. The first step is to check for out of range values and then to orient all item scores so that high scores correspond to better health. Each of the item scores is oriented so that a higher score represents better health. Values for items 1, 7 and 8 will be recorded using weights derived from Likert analyses. For item 1, excellent is scored 5.0, very good=4.4, good=3.4, fair=2.0 and poor=1.0. For item 7, none=6.0, very mild=5.4, mild=4.2, moderate=3.1, severe=2.2 and very severe score=1.0. Scores for item 8 take accounts of the answers to item 7: if pain is recorded on either item, then item 8 is scored 6. If item 8 is answered not at all, but item 7>none, then item 8 is scored 6. If item 8 is answered not at all, but item 7>none, then item 8 is scored 5. For the remaining categories of item 8, a little bit =4, moderately =3, quite a bit=2, and extremely =1. Next, scores for items on each of the eight scales are added to give scale scores. Next, scores for items on each of the eight scales are added to give scale scores. Finally these are linearly transformed to a 0 to 100 scale [16]. Formula is: Transformed scale = (actual score-lowest possible score)/possible raw score range x 100.²

Table 2.2:- Meaning of SF-36 Scores

Concepts	No. of items	Meaning of scores	
		Low scores	High scores
Physical functioning	10	All types of physical activities including bathing or dressing performing limited a lot	All types of physical activities including the most vigorous performs without limitations due to health.
Role limitations due to physical problems	4	Problems with work and other daily activities due to physical health	Past 4 weeks, No problems with work and other daily activities due to physical health
Social Functioning	2	Very Extreme and frequent interference in normal social activities due to physical and emotional problems	Past 4 weeks, Performs normal social activities without interference due to physical and emotional problems
Bodily Pain	2	Very severe and extremely. Limitation due to pain	Past 4 weeks, No pain or limitations due to pain
General mental Health	5	Feelings of nervousness and depression all of the time.	Past 4 weeks, Feels peaceful, happy and calm all of the time.
Role limitations due to emotional problems	3	Problems with work and other daily activities due to emotional problems	Past 4 weeks, No problems with work and other daily activities due to emotional problems.
Vitality	4	Feels all time of tired and worn out.	Feels full of pep and energy of the time, past 4 weeks
General health perceptions	5	Trust in personal health is poor and likely to get worse	Trust personal health is Excellent.

Results and Discussion:-

Total number of One hundred thirty patients were enrolled in the study. By Simple Sequential Randomization technique, two group of patients were equally divided one placebo group and another treatment group. a) All odd number of enrolled patients were given placebo medication (65 patients). b) All even number of enrolled patients were given treatment (i.e. Arnica 30c) medication (65 patients). All patients completed the first follow up therapy during 30 days. Overall 12 patients did not complete the therapy for unknown reasons during the completion of 120 days (After 30 days 4 patients were dropped out, after 60 days 6 patients were dropped out and after 90 days 3 patients were dropped out). In total 9 patients were dropped out from placebo group and 3 patients were dropped out from treatment group. These 12 drop out patients were included in the statistical analysis in analogy with intention to treat concept¹, as they were unimproved (i.e. by using the score of the previous questionnaire values).

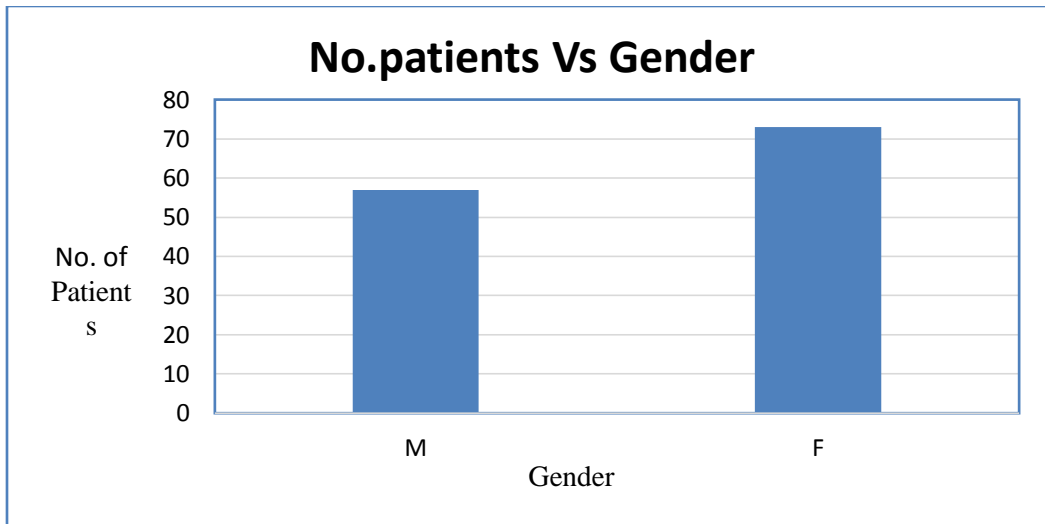
Demographic data of patients:-

Present characteristics of the migraine patients

Table-3.1:- Present characteristics of migraine patients

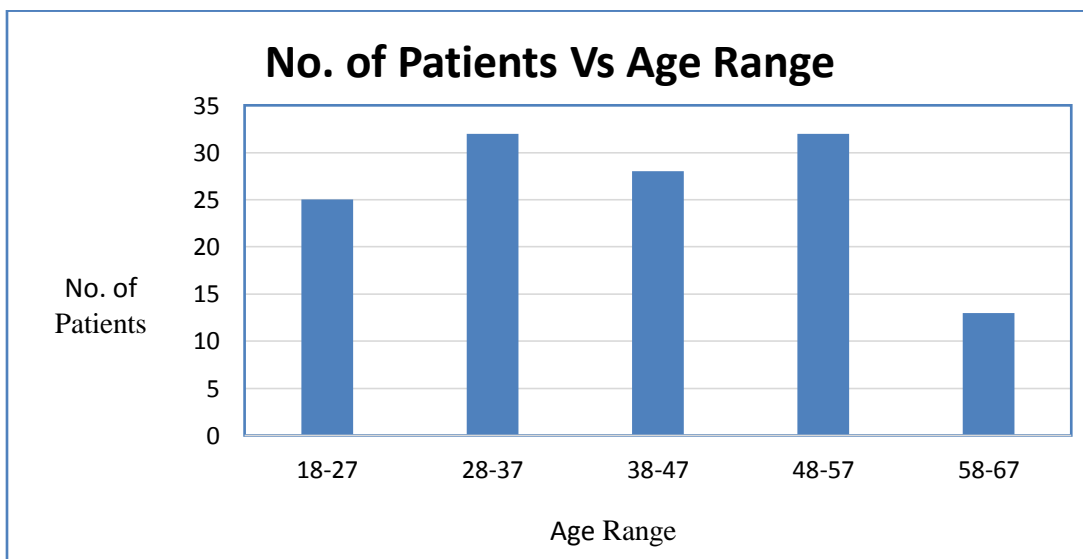
Variable	Value		Total
Gender	Male(M)	57	130
	Female(F)	73	

Age Range			
18-27	25		130
28-37	32		
38-47	28		
48-57	32		
58-67	13		
Marital Status			
	Married	Un Married	130
Male	43	12	
Female	65	10	
Total	108	22	



Graph: 3.0:- Graph of gender

As shown in Table 3.1 total 130 patients were enrolled in which 57 patients of migraine were male and other 73 migraine patients were female. Number of married patients of male patients are 43 and unmarried patients counts 12. Number of married patients of female patients are 65 and unmarried patients counts 10. Prevalence of migraine was found to be more in female as compare to male in Saurashtra region. Moreover, married females are shown to have more prevalence of migraine.



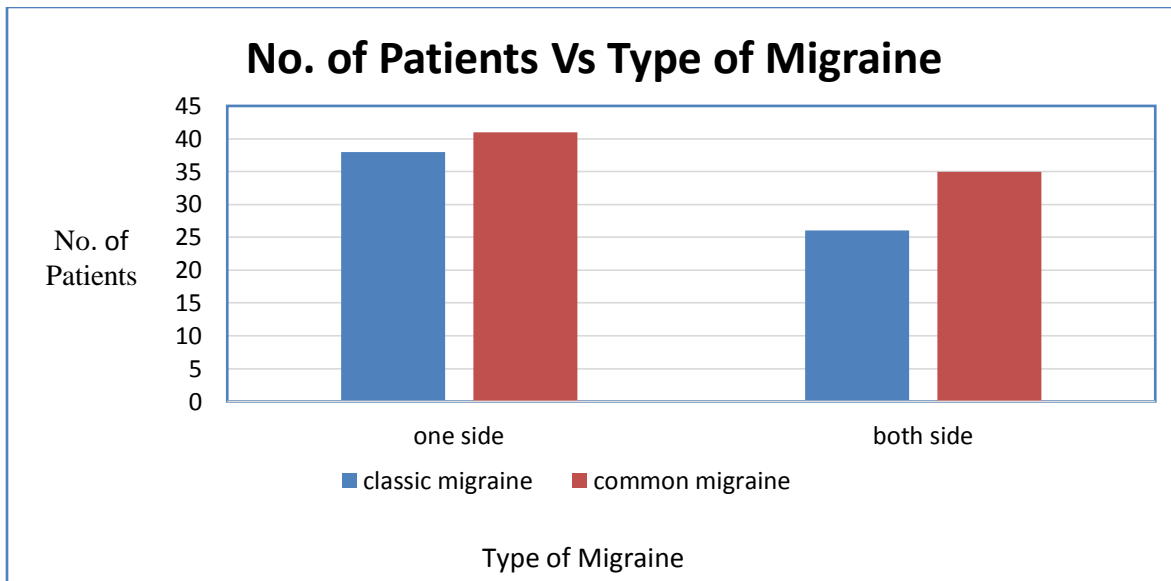
Graph: 3.1:- Age range of migraine patients

According to our study, the prevalence of migraine is highest among people having range of age range of 28-37 and 48-57 years. Data suggests that migraine patients were more prevalent in working age.

Type of migraine:-

Table-3.2 :- Type of migraine

Type of migraine	One side	Both side
Classic migraine	38	26
Common migraine	41	35



Graph: 3.2:- Type of migraine

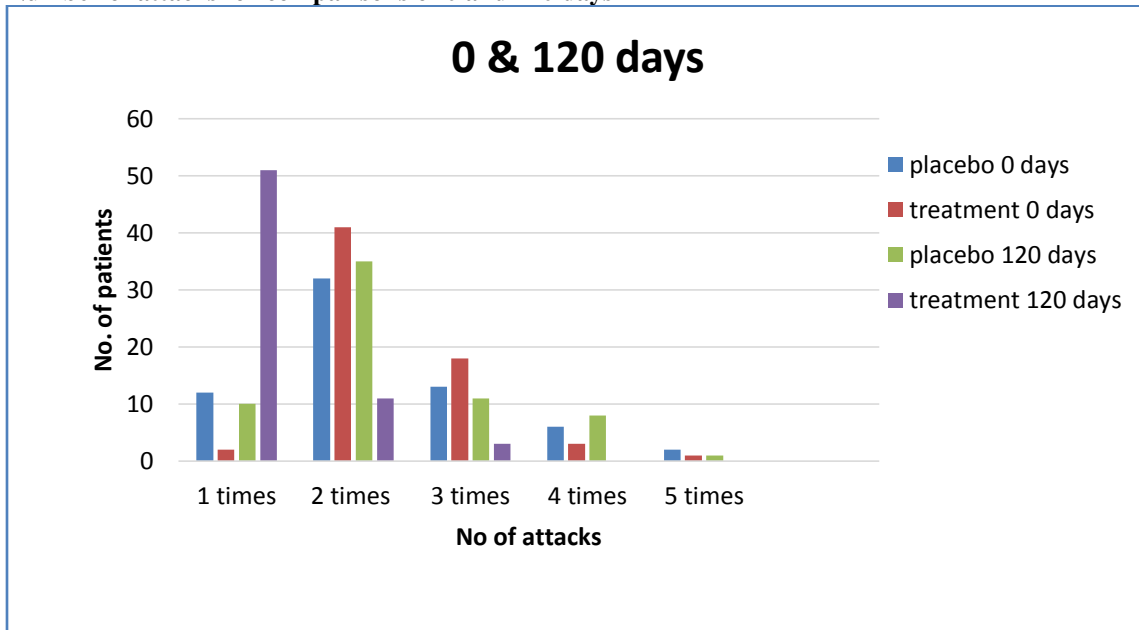
Out of 130 patients enrolled for study ,38 patients were suffering from classic migraine on one side of head and 26 patients are suffering from both side of head in classic migraine.41 patients are suffering from common migraine on one side and 34 patients are suffering from both sides of common migraine.

Disease Characteristics of patients:-

Table-3.3:- Number, Intensity and Duration of migraine attacks of 0 day and 120 days

No. of attacks per month	0 day		120 days	
	Placebo	Treatment	Placebo	Treatment
1 times	12	2	10	51
2 times	32	41	35	11
3 times	13	18	11	3
4 times	6	3	8	0
5 times	2	1	1	0
Intensity of attacks				
Mild	0	0	7	29
Moderate	28	41	39	33
Severe	37	24	19	3
Duration of attacks				
< 1hr	12	26	4	31
1-2 hr	22	10	13	26
2-3 hr	24	23	39	5
3-6 hr	7	6	9	3

Number of attacks for comparisons of 0 and 120 days

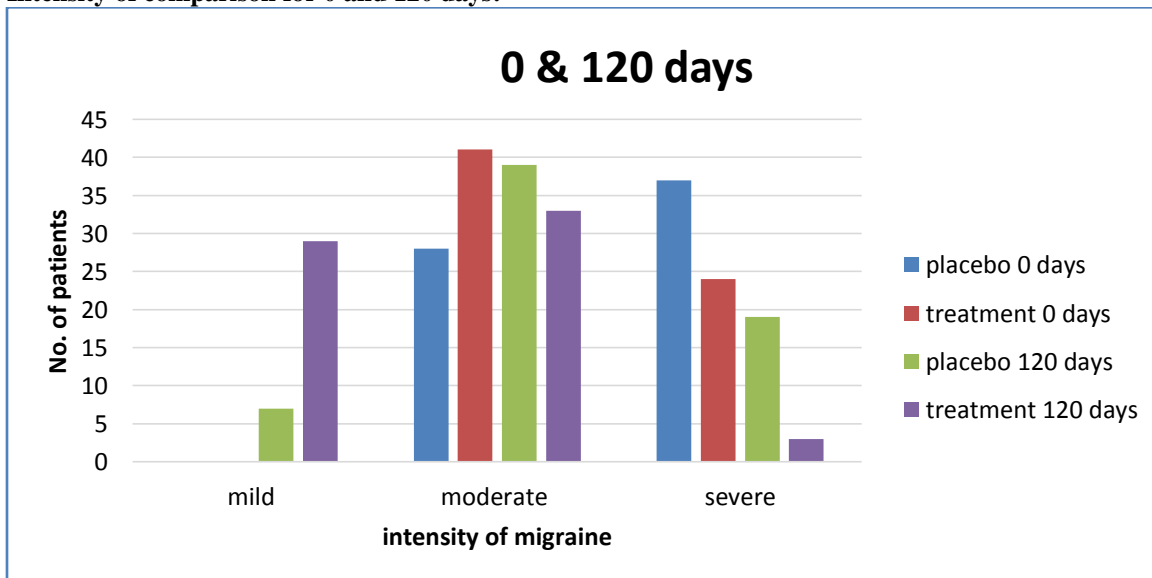


Graph 3.3:- Number of attacks for comparison of 0 and 120 days

Arnica 30c was found to decrease the intensity, frequency and duration of migraine attacks in treatment group than placebo group as shown in Table 3.3.

Number of attacks:Patients receiving Arnica 30c were shown to have decrease in frequency of migraine attacks as compare to placebo after 120 days of study.(Treatment group: n=51,78.4%; Placebo group: n=10, 15.3%, {1 times}).

Intensity of comparison for 0 and 120 days:-

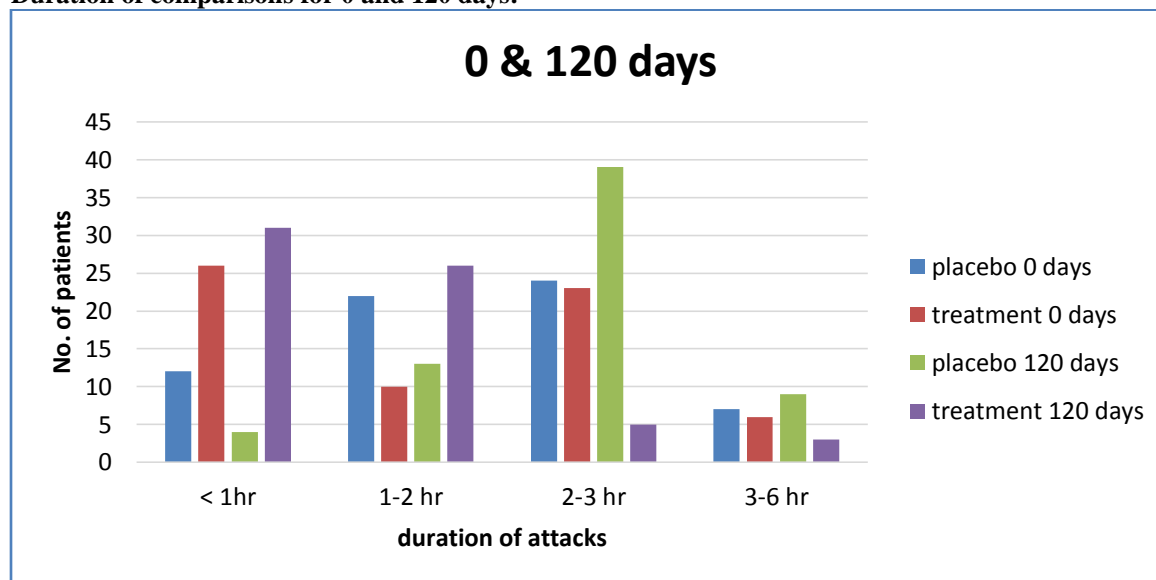


Graph 3.4:- Intensity of comparisons for 0 and 120 days

Intensity of attack: Patients from the treatment group also experienced the reduction in intensity of migraine attack rather than placebo group of patients after 120 days of study. In treatment group n=29 (44.6%) of patient felt reduction in intensity of migraine as compare to n=7(10.7 %) in placebo group. The pool of patients receiving

Arnica 30c was found to be shifted from severe to moderate and mild intensity in migraine attacks (Table 3.3) at the end of treatment of 120 days.

Duration of comparisons for 0 and 120 days:-



Graph 3.5:- Duration of comparison for 0 and 120 days

Duration of migraine attack: As shown in Table 3.3 and Graph 3.5 there was reduction in duration of migraine attack in group receiving Arnica 30c. (Treatment group: n= 31, 47.6% of patients were found to have the duration of attack less than 1 hour in treatment group whereas in placebo group only n=4,6.1% of patients were found to have the duration of attack less than 1 hour of migraine attack). Maximum benefits of Arnica 30c were found to be observed in treatment group after 120 days having duration 2-3 hr.

SF-36 Statistical Analysis for various parameters after 0 day in placebo and treatment groups.

Table 3.4:- Statistical analysis of SF 36 for 0 day

SF 36 Dimensions	0 day		Median	
	Mean ± SEM (SD)	Mean ± SEM (SD)	Placebo	Treatment
	Placebo	Treatment		
Physical functioning (PF)	63.30±2.34(18.92)	65.46±2.2(18.40)	70	70
Role limitation due to physical problems (RP)	60.38±3.59(28.94)	65.38±3.66(29.54)	50	75
Bodily pain(BP)	48.42 ± 2.92(23.54)	49.96± 3.2 (25.94)	47.5	47.5
Mental health(MH)	48.24±0.93(7.51)	49.35±1.41(9.20)	48	52
Role limitation due to emotional problems (RE)	72.31±3.54(28.1)	61.02±4.29(34.65)	66.7	66.7
Vitality(VT)	49.38±1.34(10.84)	49.92±1.30(10.55)	50	50
Social functioning(SF)	45.96±3.041(24.51)	43.84±2.63(21.20)	50	50
General health(GH)	52.30±1.49 (12.02)	49.76±1.25(10.13)	50	50

N=130 (statistical insignificant, P>0.05)

SF-36 shows insignificant ($P>0.05$) for 0 day since all the patients were just enrolled in the study as shown in Table 3.4.

Physical Component Summary and Mental Component Summary Measure for 0 day

All value are expressed in Mean \pm SEM, n=130

Table 3.5:- Effect on PCS and MCS (0 day)

	PCS		MCS	
	Placebo	Treatment	Placebo	Treatment
0 day	40.66 \pm 0.722	40.2 \pm 0.511	42.86 \pm 0.759	41.13 \pm 0.742

Three scales (PF, RP and BP) correlate most highly with the physical component and contribute most to the scoring scale of the physical component summary (PCS) measure. The mental component summary correlates to the three scales (MH, RE and SF) scale. Three of scale (VT, GH and SF) have notably correlates with both components. From Table 3.5 it can be clear that the patients were just enrolled and so the PCS and MCS were found statistically insignificant ($P>0.05$). It is important to note here, scale that load highest on the physical component are most responsive to treatments that change physical morbidity, whereas scale loading highest on the mental component respond most to drugs and therapies that target mental health.

Statistical Analysis of various parameters of SF-36 after 60 and 120 days of medication for placebo and treatment group.

Table 3.6:- Statistical Analysis of SF-36 for 60 and 120 days

SF-36 dimensions	60 days		Median		120 days		Median	
	Mean \pm SEM (SD)	Mean \pm SEM (SD)	Placebo	Treatment	Mean \pm SEM (SD)	Mean \pm SEM (SD)	Placebo	Treatment
Physical functioning(PF)	55.46 \pm 2.02(16.29)	56.53 \pm 1.81 (14.60)	55	60	34.23 \pm 2.69 (21.6)	77.69 \pm 1.63 (13.17)*	25	75
Role Limitation to Physical Problem (RP)	48.46 \pm 4.27(34.48)	46.61 \pm 4.55 (36.74)	50	50	21.53 \pm 3.79(30.57)	81.53 \pm 2.212 (17.83)*	0	75
Bodily pain (BP)	66.53 \pm 1.76(14.25)	68.11 \pm 1.97 (15.88)	67.5	67.5	40.3 \pm 2.2 (18.07)	74.23 \pm 1.95 (15.79)*	32.5	77.5
Mental Health (MH)	48.98 \pm 1.12(9.02)	50.06 \pm 0.90 (7.30)	48	52	48.36 \pm 1.37 (11.06)	52.30 \pm 1.48 (11.98)	48	52
Role Limitation to Emotional Problem(RE)	44.60 \pm 4.21(34.00)	42.50 \pm 4.54 (36.63)	33.3	33	23.58 \pm 4.051 (32.66)	86.16 \pm 2.62 (22.15)*	0	100
Vitality(VT)	51.15 \pm 1.02(8.8)	52.84 \pm 0.890 (7.17)	50	55	46.69 \pm 1.55(12.57)	52.69 \pm 2.115 (17.04)*	45	50
Social Functioning(SF)	58.65 \pm 1.97(15.92)	57.19 \pm 1.91 (15.40)	62.5	62.5	42.69 \pm 2.67(21.525)	74.42 \pm 1.888 (15.21)*	37.5	75
General Health(GH)	56.23 \pm 1.35(10.89)	56.53 \pm 1.18 (9.55)	55	55	43.38 \pm 1.05(8.5)	55.84 \pm 1.20 (9.70)*	45	55

N=130, *= Statistical significant ($P<0.05$)

Results of SF-36 at the end of 60 days of medication showed improvement in parameters like Physical Functioning, Bodily Pain, Mental health, Vitality and General Health in treatment group as compared to placebo group but increase in these parameters was found to be statistically insignificant ($P>0.05$). Few parameters like Role limitation due to physical problem, Role limitation due to emotional problem and Social Functioning were found to be decreased in treatment group as compared to placebo group but decrease in these parameters was found to be statistically insignificant ($P>0.05$).

Results of SF-36 at the end of 120 days of medication showed improvement in all parameters of SF-36 like Physical Functioning, Bodily pain, Mental health, Vitality, General Health, Role limitation due to physical problem, Role limitation due to emotional problem and Social Functioning in treatment group as compared to placebo group. Increase in these parameters was found to be statistically significant ($P<0.05$) except mental health whose increase was found to be not quite significant as compared to placebo group ($P>0.05$).

Physical Functioning (PF):-

Mean \pm SEM for PF was 77.69 ± 1.63 and median was 75 for treatment group whereas in placebo group PF was 34.23 ± 2.69 and median was 25, which is lower value than treatment group. Score scale shows significant changes in treatment group than placebo group ($P<0.05$). Higher score in PF scale in treatment group suggests that it performs all type of physical activities including the most vigorous activities without limitation due to health than placebo group after 120 days of study.

Role limitation due to physical health problem (RP):-

Mean \pm SEM for RP was 81.53 ± 2.212 and median was 75 for treatment group whereas in placebo group RP was 21.53 ± 3.79 and median was 0 which is lower value than treatment group. Score scale showed significant change in treatment group than placebo group ($P<0.05$). Higher score in treatment group indicates that no problem with work and or other daily activities because of physical health than placebo group after 120 days.

Bodily Pain (BP):-

Mean \pm SEM for (BP) was 74.23 ± 1.95 , median was 77.5 for treatment group whereas in placebo group BP was found 40.3 ± 2.2 and median was 32.5 which is lower value than treatment group. Score scale shows significant changes in treatment group than placebo group ($P<0.05$). Higher score in treatment group indicates that no pain and limitation due to pain than placebo group after 120 days.

Mental Health (MH):-

Mean \pm SEM for MH was 52.30 ± 1.48 , median was 52 for treatment group whereas in placebo group MH was found 48.36 ± 1.37 and median was 48. Score scale shows insignificant changes in treatment group than placebo group ($P>0.05$). Score in treatment group indicates that patients were feel quite calm, peaceful happy all of the time than placebo group after 120 days of study.

Role limitation due to emotional problems (RE):-

Mean \pm SEM for RE was 86.16 ± 2.62 , median was 100 for treatment group whereas in placebo group RE was found 23.58 ± 4.051 and median was 0, which is lower value than treatment group. Score scales shows significant changes in treatment group than placebo group ($P<0.05$). Higher score in treatment group of patients indicate that patients have no problem with work or daily activities due to emotional problem than placebo group after 120 days of study.

Vitality (VT):-

Mean \pm SEM for VT was 52.69 ± 2.115 , median was 50 for treatment group where as in placebo group VT was found 46.69 ± 1.55 and median was 45 which is lower value than treatment group. . Score scales shows significant changes in treatment group than placebo group ($P<0.05$). Higher score in treatment group of patients indicates that patients feels full of pep and energetic all of the time than placebo group after 120 days of study.

Social Functioning (SF):-

Mean \pm SEM for SF was 74.42 ± 1.888 , median was 75 for treatment group where as in placebo group SF was found 42.69 ± 2.67 and median was 37.5 which is lower value than treatment group. Score scales shows significant changes in treatment group than placebo group ($P<0.05$). Higher score in treatment group of patients indicates that patients performing normal social activities without interference due to physical or emotional than placebo group after 120 days of study.

General Health (GH):-

Mean \pm SEM for GH was 55.84 \pm 1.20, median was 55 for treatment group where as in placebo group GH was found 43.38 \pm 1.05 and median was 45 which is lower value than treatment group. Score scales shows significant changes in treatment group than placebo group ($P < 0.05$). Higher score in treatment group of patients indicates that patients believes that personal health is excellent than placebo group after 120 days of study.

Physical Component Summary and Mental Component Summary Measures after 60 and 120 days of medication for placebo and treatment group:-**Table 3.7:-** Effect on PCS and MCS (0,60 and 120 days)

Days	PCS		MCS	
	Placebo	Treatment	Placebo	Treatment
0 day	40.66 \pm 0.72	40.20 \pm 0.51	42.86 \pm 0.76	41.13 \pm 0.74
60 days	39.20 \pm 0.65	39.80 \pm 0.68	43.60 \pm 0.77	43.70 \pm 0.73
120 days	30.30 \pm 1.02	48.49 \pm 0.68	42.60 \pm 0.69	46.18 \pm 0.685

All values are expressed in Mean \pm SEM, n=130

Results of PCS and MCS at the end of 60 days of medication was found to be improved in treatment group as compared to placebo group but this increase was statistically insignificant ($P > 0.05$). Results of PCS and MCS at the end of 120 days of medication was found to be improved in treatment group as compared to placebo group (i.e. 48.49 \pm 0.68 and 46.18 \pm 0.685) were as compared to placebo group (30.3 \pm 1.02 and 42.60 \pm 0.69) after 120 days of study respectively} where increase in the PCS and MCS of treatment group was found statistically significant ($P < 0.05$). From the study of 0 day to 120 days, PCS and MCS was found to be decreased in placebo group of patients at the end of 120 days. Dummy medications (i.e. placebo) are thought to have role in management of some CNS disorders including migraine. But from the present data it can be suggested that due to this there is no improvement in quality of life of patients of migraine. Both PCS and MCS in the treatment group were found to be improved at the end of 120 days of study (Table 3.7), which indicates improvement in quality of life of patients receiving Arnica 30c. Higher score in treatment group indicates improvement in all scales which shows quality of life in migraine patients were improved in treatment group with Arnica 30c as compared to placebo group.

Conclusion:-

From the present study it may be concluded that in the region of Rajkot prevalence of migraine is more in female as compared to male. Married females were also found to have more prevalence of migraine. It is important to note that migraine occurs among working age of the people which may result in loss of the productive hours thus leading to social and economic burden in addition to physical and mental problems. Common migraine (migraine without aura) with a pattern of unilateral pain was found to be most prevalent type of migraine found in present study. Effect of treatment of Arnica 30c was assessed by prospective approach in present study by SF-36 method. It is found that Arnica 30c not only decreases frequency but also intensity and duration of migraine attacks. Comparison of SF-36 parameters after 120 days reveals that there is significant improvement in PF (Physical Functioning), RP (Role limitation due to physical problem), BP (Bodily Pain), GH (General Health), VT (Vitality), SF (Social Functioning), RE (Role limitation due to emotional problem) among treatment group compared to placebo group. It shows that there is no psychological effect (i.e. due to placebo medication) in the improvement of quality of life in patients. These parameters further expressed collaboratively as physical component summary and mental component summary were also found to increase significantly in treatment group than placebo group. Thus, Arnica 30c treatment effectively and efficiently reduces the symptoms of migraine in a span of 120 days. Thus, use of Arnica 30c homeopathic treatment can be a potentially useful remedy for improvement of quality of life in patients of migraine. It is suggested that long term multi-centric clinical studies with a larger pool of patients will provide better understanding of efficacy for Arnica 30c homeopathic treatment.

Conflict of Interest:-

The authors have no conflict of interest

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